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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/084,235 | 02/25/2002 | Michael John Reed | 674519-2001.4 | 6335 |

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| EXAMINER | |
|---|---|
| BADIO, BARBARA P | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1616 | |

DATE MAILED: 11/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application N . | Applicant(s) | |
|---|---|---|---|
| | 10/084,235 | REED ET AL. | |
| | Examiner | Art Unit | |
| | Barbara P. Badio, Ph.D. | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☐ Claim(s) *6-20* is/are pending in the application.

4a) Of the above claim(s) *12-16 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-11,17,18 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3&4*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

**First Office Action on the Merits**

1. Applicant's election with traverse of Group I and the species of oestrone-3-sulphamate in Paper No. 6 is acknowledged. The traversal is on the ground(s) that any search for the compositions of Group I will encompass references for the compositions of Group II. This is not found persuasive because the compounds of the two Groups are distinct in structure and, thus, are independent of each other. Thus, a search of compositions containing steroidal compounds (i.e., Group I) would not encompass or result in references for compositions containing nonsteroidal compounds (i.e., Group II).

The requirement is still deemed proper and is therefore made **FINAL**.

2. Based on applicant's election of Group I, claims 6-20 will be examined to the extent they read on compositions comprising compounds wherein the polycycle moiety is a steroid moiety.

***Claim Objections***

3. Claims 12-16 and 19 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

***Doubl Patenting***

4. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

5. Claim 8 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 2 of prior U.S. Patent No. 6,187,766. This is a double patenting rejection.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 6-11, 17, 18 and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,616,574. Although the conflicting claims are not identical, they are not

patentably distinct from each other because they both encompass steroid sulphamates such as estrone-3-sulphamate. The difference between the present invention and the patent is in the scope of the claimed compounds. The present application, unlike the cited patent, recites non-steroidal compounds.

8. Claims 6-11, 17, 18 and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,187,766. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass steroid sulphamates such as estrone-3-sulphamate. The difference between the present invention and the patent is in the scope of the claimed compounds. The present application, unlike the cited patent, is limited to polycycle sulphamates.

9. Claims 6-11, 17, 18 and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,642,397. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to add a pharmaceutical carrier to the compounds of the cited patent.

10. Claims 6, 7, 9-11, 17, 18 and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 12-20 of copending Application No. 09/755,429. Although the conflicting

claims are not identical, they are not patentably distinct from each other because they both encompass steroid sulphamates such as estrone-3-sulphamate. The difference between the present invention and the patent is in the scope of the claimed compounds. The present application, unlike the latter application, is limited to polycycle sulphamates.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 6-11, 17, 18 and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-5 of copending Application No. 09/794,853. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass steroid sulphamates such as estrone-3-sulphamate and it would be obvious to add a pharmaceutical carrier to the compounds of the above-mentioned application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 6-11, 17, 18 and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 and 28-30 of copending Application No. 10/013,798. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass steroid sulphamates such as estrone-3-sulphamate. The difference

between the present invention and the patent is in the scope of the claimed compounds. The present application, unlike the latter application, is limited to polycycle sulphamates.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 6-11, 17, 18 and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 9-11 of copending Application No. 10/165,599. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass steroid sulphamates such as estrone-3-sulphamate. The difference between the present invention and the patent is in the scope of the claimed compounds. The present application, unlike the latter application, is limited to polycycle sulphamates.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 6-11, 17, 18 and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 and 39-42 of copending Application No. 10/367,622. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass steroid sulphamates such as estrone-3-sulphamate. The difference between the present invention and the patent is in the scope of the claimed compounds. The present application, unlike the latter application, recites non-steroidal compounds.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 6-11, 17, 18 and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 and 19 of copending Application No. 09/572,237. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass steroid sulphamates. The difference between the present invention and the patent is in the scope of the claimed compounds. The latter application, unlike the present application, is limited to oxime derivatives of said sulphamates.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Note: The cited application was allowed but has not issued as a patent.

***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 6-11, 17, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Registry Handbook (1984 Supplement) in view of Schwarz et al. (DD 114806) and Hirsch ('351).

The handbook teaches RN 91490-65-2, 19-norpregna-1,3,5(10)-trien-20-yne-3,17-diol,3-sulfamate (see attached).

According to (a) MPEP § 2121.02, "[I]t is possible to make a 35 U.S.C. 102 rejection even if the reference does not itself teach one of ordinary skill how to practice the invention, i.e., **how to make** or use the article disclosed" and (b) MPEP § 2131.01, multiple references can be utilized in making a rejection under 35 U.S.C. 102 rejection (see especially section I). The following articles are presented to show the level of skill of the ordinary artisan at the time of the present invention.

Schwarz et al. teach the production of steroid sulphamates by reaction of a sterol and a sulfamoylchloride ( i.e., R-OH + (R, R')N-SO2-Cl --> R-OSO2-N(R, R') ) (see the entire article, especially Examples 1-10 and claim 1). The reference also teaches the use of steroid sulphamates in fertility control in humans and animals (see page 2, col. 2, lines 52-59).

Hirsch teaches the production of aliphatic sulphamates utilizing similar process (see the entire article, especially col. 1, lines 31-48). The reference also teaches the use of sulfamoyl halides such as sulfamoylchloride and mono/disubstituted sulfamoyl halides (see col. 1, lines 37-39).

Based on the teachings of Schwarz et al. and Hirsch, a process for the production of compound, RN 91490-65-2, would have been obvious to the skilled artisan in the chemical art at the time of the present invention.

The instant claims recite a composition comprising the compound taught by the Registry Handbook. However, addition of a carrier or solvent to an unpatentable compound is prima facie obvious. See ***Ex parte Douros***, 163 USPQ 667.

## ***Telephone Inquiry***

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308- 2927. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
November 13, 2003